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ROLE OF TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) VERSUS CONVENTIONAL AORTIC VALVE REPLACEMENT IN THE TREATMENT OF AORTIC VALVE DISEASE

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Abstract

Conventional aortic valve replacement (AVR) surgery has been in clinical use since 1960. Results, particularly in high-risk populations such as the very elderly and frail, continue to improve in response to the challenges posed by this growing segment of the patient population. Transcatheter aortic valve implantation (TAVI) is a fairly recent development, performed for the first time in 2002. The last decade has seen an exponential growth in the application of this technology in higher-risk populations. Results of recent randomized prospective trials demonstrate both the future promise and current problems of the TAVI approach. Many patients deemed inoperable for AVR have been treated successfully by TAVI. However, elevated procedural and late mortality rates, excessive early and late stroke, and a significant incidence of periprosthetic aortic valve insufficiency and patient-prosthesis mismatch all suggest caution in extending this technology to patients able to undergo conventional AVR with a low risk of early or late complications.

Introduction

The first successful surgical implantation of an aortic valve prosthesis was reported by Harken et al. in 1960.[1] Many patients who had been terminally ill from aortic valve stenosis or insufficiency and unresponsive to medical therapy could now be restored to good health. Over the ensuing 50 years, numerous innovations and refinements of these early techniques and prostheses have been developed.[2]

In 2002, Cribier reported the first transcatheter aortic valve implant (TAVI) in a human subject for treatment of calcific aortic stenosis.[3] Since then, another era has opened for patients with critical calcific aortic stenosis (AS) who had been considered too ill for conventional surgical AVR. Now, a decade later, there is good evidence that TAVI represents a true treatment advance for AS patients who are considered too ill to undergo AVR. In these carefully selected patients, TAVI has produced a markedly improved survival and relief of symptoms. In the United States, TAVI using the Edwards SAPIEN device is now approved by the FDA for use in patients considered too sick for conventional AVR and who have a calcified aortic annulus.

Throughout its history, however, TAVI has been associated with the risk of five persistent major complications: high perioperative and late mortality, elevated early and late stroke rates; major vascular complications; patient prosthesis mismatch; and the occurrence of significant and progressive post-implant periprosthetic insufficiency. Additionally, the long-term natural history after TAVI of the progressive proliferative disease that causes calcific AS is unknown.

Results of the PARTNER Trial

The PARTNER trial represents the most definitive data available to compare TAVI with other therapies. The PARTNER Cohort B randomized prospective trial compared the results of TAVI in 179 patients considered to be surgically inoperable for AVR with standard medical therapy (including balloon aortic valvuloplasty if needed) in 179 similarly ill control patients.[4] In the TAVI group, 30-day mortality was 6.4%. At 1 year the overall mortality for TAVI was 30.7% vs. 50.7% for standard therapy (P <0.0001). The overall stroke rate at 1 year was 10.6% vs. 4.5% for standard therapy

• Bicuspid or noncalcified aortic valve
• Aortic annulus diameter (echo measurement) <18 mm or >25 mm
• Aortic dissection or iliac-femoral dimensions or disease precluding safe sheath insertion (especially calcification)
• Severe LV dysfunction (LVEF <20%)
• Untreated CAD requiring revascularization
• Severe AR or MR (>3+) or prosthetic valve (any location)
• Serum creatinine >3.0 mg/dL or dialysis dependent
• Acute MI within 1 month
• Upper GI bleed within 3 months
• CVA or TIA within 6 months
• Any cardiac procedure, other than BAV, within 1 month or within 6 months for DES
• Hemodynamic instability (e.g., requiring inotropic support)

Table 1. Key exclusion criteria for PARTNER trial.[3]
LV: left ventricular; LVEF: left ventricular ejection fraction; CAD: coronary artery disease; AR: aortic regurgitation; MR: mitral regurgitation; MI: myocardial infarction; GI: gastrointestinal; CVA: cerebrovascular accident; TIA: transient ischemic attack; BAV: Balloon aortic valvotomy; DES: drug-eluting stent.

(P = 0.04). At 1 year the incidence of significant paravalvular leak was unchanged at 12.2% and the rate of relief of aortic stenosis in the TAVI group was stable. At 2 years of follow-up, the overall mortality was 43.3% for the TAVI patients and 67.6% for those receiving standard care.[5] The stroke rate at 2 years had risen to 13.8% in the TAVI group and 5.5% in the standard group (P = 0.009). Of the 61 patients alive with echo data at 30 days and 2 years, the paravalvular AI with TAVI was improved in 42.6%, unchanged in 41%, and worse in 16.49%. Relief of severity of aortic stenosis was well maintained in the TAVI group at 2 years, with a mean gradient of 10.6 mm and aortic valve effective area of 1.68 cm^2. Thus the 2-year data from the Partner Cohort B study continues to confirm the view that TAVI should be seriously considered for patients who are not deemed operable with AVR and who fit the selection criteria of the PARTNER Cohort B trial, including the many exclusion criteria shown in Table 1. The very high early and late mortality and morbidity in some of the most severely ill of these already critically ill patients suggest that some patients may be too ill to even tolerate TAVI.

Cohort A of the PARTNER trial reported the role of TAVI as a replacement for conventional AVR in patients thought to be operable but who have a higher predicted risk for surgery.[6] In addition to the exclusion criteria shown in Table 1, these patients were expected to have a score of at least 10% on the Society of Thoracic Surgeons risk model. The predicted surgical mortality for the patients enrolled was 11.8%. The results of this study documented an "as treated" 30-day mortality of 5.2% for TAVI and 8.0 % for AVR, a nonsignificant difference (P = 0.15). Survival at 1 year was also similar: TAVI 24.2%, AVR 26.8% (P = 0.44). The stroke rate at 30 days was 5.5% for TAVI and 2.4% for AVR, a significant difference (P = 0.04), and at 1 year it was 8.3% vs. 4.3% (P = 0.04). At 30 days post-operatively, gradient reduction was similar, and significant periprosthethic leaks were present in 12.2% of TAVI patients vs. 0.9% for AVR.

The seriousness of the occurrence of moderate or severe regurgitation after TAVI was recently reported by Sinning et al. in 108 consecutive patients.[7] At 2 years of follow-up, overall mortality was 31.4%. Patients with no residual aortic paravalvular regurgitation had a mortality of 18%; it was 31% with grade 1 and 67% with grade ≥2 aortic regurgitation. They concluded that moderate to severe periprosthetic aortic regurgitation is a strong predictor of adverse short and midterm outcome after TAVI. In the U.K. TAVI Registry report, moderate to severe aortic insufficiency was reported to be an important univariate and multivariate predictor of mortality at 1 year.[8] Thus significant periprosthetic aortic insufficiency is established as a serious complication and occurs in a significant proportion of patients undergoing TAVI.

A little-noted but important problem in the design of the high-risk portion of the Cohort A PARTNER study was the inclusion of patients who had undergone previous coronary artery bypass surgery (CAB). Therapy by catheter does not involve a redo chest surgical procedure. The death rate at 1 year in the patients undergoing redo chest AVR after CAB was 19.1% (29 of 152), and the death rate in patients older than 85 years was 26.1%. These figures are high for surgical patients and disproportionately affected the overall surgical mortality. Stortecky et al. compared TAVI vs. AVR in patients with aortic stenosis and a previous CAB, and they reported a perioperative mortality for AVR after CAB of 2.5%.[9] Thus, in terms of an unbiased comparison of TAVI and isolated aortic valve replacement for aortic stenosis, the CAB patients would have been better omitted.

Comparison of Current Indications for TAVI vs. AVR

	TAVI	AVR
Isolated calcific AS	+	+
AS/AI	-	+
MR >3, mitral, tricuspid repair	-	-
Bicuspid aortic valve	-	+
Dilated aortic annulus	-	+
Choice of prosthesis, mechanical vs. tissue	-	+
Associated ascending aneurysm	-	+
Associated CAB	-	+
Poor LV function	-	+
Small aortic root enlargement	-	+

Table 2. Differences in indications for TAVI vs. AVR.
AS: aortic stenosis; AI: aortic insufficiency, MR: mitral regurgitation; CAB: coronary artery bypass; LV: left ventricular.

Results of Conventional AVR in Patients Similar to the PARTNER Trial Cohort A (High-Risk Group)

At the American Heart Association 2008 annual meeting, I reported on the risk of AVR in 1,223 of my patients, of whom 203 were older than 80 years of age.[10] This data was updated in 2011 to include 1,514 patients operated on in our surgical service. Of these, 256 were over 80 years of age, and 92 of these patients underwent isolated AVR. These patients were similar to the PARTNER high-risk group in age, sex, pre-op ejection fraction, and severity of aortic stenosis. The perioperative mortality was 2.7% (3 of 92), and the perioperative stroke rate was 4.3% (4 of 92). The 1-year survival rate was 85% (Kaplan-Meier). There were no periprosthetic leaks. These outcomes indicate that in selected elderly patients treated in an experienced center, surgical results superior to those receiving AVR in the PARTNER trial high-risk cohort can be achieved with fewer late complications such as ongoing strokes and progressive aortic insufficiency.

Current Intrinsic Limitations of TAVI

A comparison of the capabilities of TAVI vs. AVR is shown in Table 2. In our unselected total series of 1,514 AVR patients, only 44% had undergone an isolated AVR. The remainder have received concurrent CAB, ascending aortic aneurysm repair, or mitral or tricuspid valve surgery. While most patients had pure aortic stenosis, about one-third had some degree of aortic insufficiency, which is a contraindication to TAVI. AVR allows treatment of any size of aortic "annulus" because prosthetic valves are available up to a diameter of 33 mm.

Ascending aortic aneurysm surgery may be required in conjunction with AVR most commonly because of atherosclerotic degeneration, Marfan's syndrome, or aneurysmal disease from bicuspid aortic valve disease. The latter may be present in a significant proportion of these patients. Bicuspid aortic valve disease is currently considered to be a contraindication for TAVI because the single-slit opening may not conform to the circular shape of the deployed prosthesis. The aortic root and ascending aorta also tend to be larger in these patients.

Patient-Prosthesis Mismatch (PPM)

The TAVI prostheses are designed to have maximal geometrical orifice area. This is achieved through direct attachment of the tissue leaflets to the stent and the absence of an external sewing ring. The Medtronic CoreValve has the leaflets attached above the "annular" fixation zone to further enhance the post-implantation effective orifice area (EOA). Despite these technical advantages, the EOA achieved by TAVI is intrinsically limited by the presence of the retained calcified aortic leaflets (which are not removed) and by the extent to which the calcified ascending aortic root and annulus can be safely dilated. In addition, the range of sizes currently available is limited.

Ewe et al.[11] reported on data from a multicenter study in which 165 patients were evaluated for PPM. Studies were performed at baseline, before hospital discharge, and 6 months after TAVI. They found that 30 patients (18.2%) had an indexed EOA of <0.85 cm^2/m^2. A substantially higher proportion of these patients with PPM did not show clinical improvement compared with those without PPM (36.7% vs. 1.5%, P <0.001). The major adverse cardiovascular- and valve-related events did not differ. In the PARTNER trial of TAVI vs. AVR for high-risk patients, data for PPM was not reported. However, postoperative aortic valve areas and gradients were slightly better for TAVI than AVR: 1.59 ± 0.48 vs. 1.44 ± 0.4 cm^2 (P = .002); 10.2 mm & 11.5 mm (P = 0.008). At 1 year, relief of symptoms was similar in both groups. The reported valve areas suggest that smaller prostheses were implanted in both groups. In addition to having no capability for aortic leaflet resection, TAVI has no capability for aortic root enlargement. Dacron patch graft angioplasty is commonly employed during AVR to enlarge small aortic roots at least one size to allow implantation of a larger conventional prosthesis.

At present, only biological prosthetic valves are available for TAVI. Mechanical valves are still considered the optimal choice in younger patients.[2] While some patients who have experienced biological valve failure may have undergone "resleeving" procedures during a second TAVI procedure, it is currently not established as a standard therapy.[12, 13] Concurrent CAB was performed in 27% to 34% of our patients. Although angioplasty would be an option in some cases, many had diffusely calcified multivessel disease.

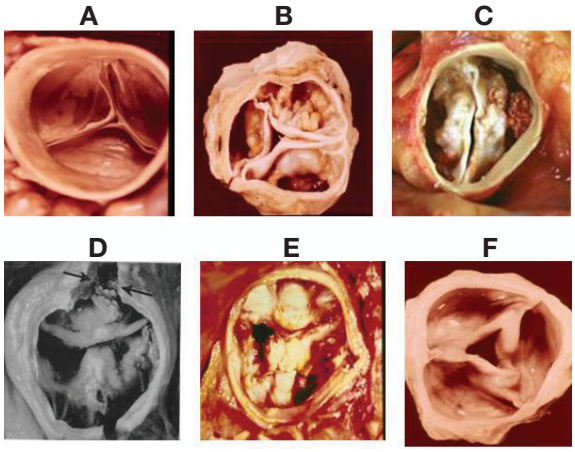

Figure 1. Aortic valve pathology. (A) Normal tricuspid valve. (B) Moderately severe calcific aortic stenosis. (C) Calcific stenosis of congenital bicuspid aortic valve. (D) Severe calcific aortic stenosis with left main coronary impingement (arrows). (E) Severe calcific aortic stenosis. (F) Rheumatic aortic stenosis with commissural fusion but no calcification of annulus or leaflets.

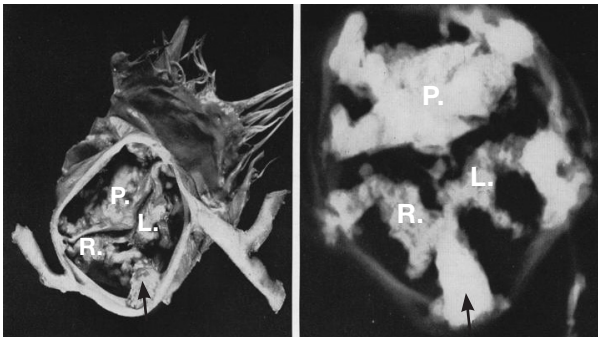

Figure 2. Severe calcific aortic stenosis (left) with radiographic study (right) showing the severe extent of calcium accumulation in the leaflets.
(Modified from Edwards JE. *An Atlas of Acquired Diseases of the Heart and Great Vessels*, Vol. 1. Philadelphia: WB Saunders; 1961. Used with permission.)

Finally, TAVI requires adequate peripheral arterial access. Peripheral vascular disease was noted to be present in 43% of the PARTNER trial patients.[4, 5]

Future Evolution of TAVI

Studies using new prostheses are attempting to overcome issues with vascular access by reducing the size of the unit that has to be introduced into the femoral artery. Thinner, steerable catheters designed to minimize contact with the aortic wall are also in development. TAVI systems that are easier to align and deploy, and can be redeployed if needed, will soon be available.

However, the current family of TAVI devices is still based on the concept of fixing the prosthesis in position by forceful dilatation and compression of the stenotic calcified aortic valve leaflet tissue. The material that must be present for this to be achieved is only available in the presence of calcific degeneration of the aortic valve, as seen in aortic stenosis; this is because the aortic valve has no annulus. AVR by surgical implantation involves resecting the diseased aortic leaflets, leaving a narrow rim at the base of the leaflet that consists of the junction of the leaflet with the aortic wall, aorto-mitral continuity, membranous septum, and the shoulder of the left ventricular myocardium. The left ventricular outflow tract begins at the lower margin of the anterior mitral leaflet and extends to where the aortic leaflets attach to the aortic wall and left ventricle; the posterior one-third to one-half consists of the aorto-mitral continuity and the anterior mitral leaflet. Thus, in the absence of the ring of calcified tissue seen with calcific aortic stenosis in the elderly, some other approach for prosthetic fixation will need to be developed.

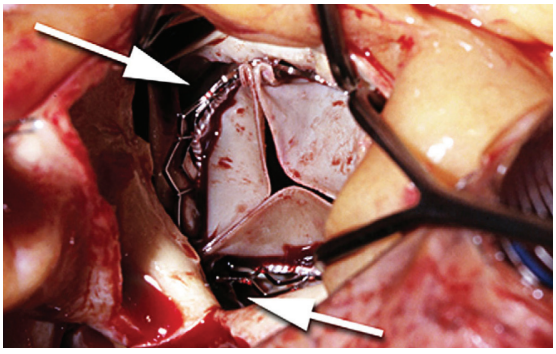

Figure 3. Intraoperative appearance of severely insufficient TAVI showing the areas of nonopposition of the prosthesis with the aortic commissure due to severe calcification.[15]
Used with permission.

In the natural history of untreated calcific aortic stenosis, the size of the obstructing calcific masses progressively increases.[14] The extent of these changes is shown in Figures 1 and 2. The disease is characterized by the formation of large exophytic masses. This material is unstable, and it is relatively easy to break off small pieces. Since the untreated disease induces death as the stenosis becomes critical, the ultimate natural history of the compressed and displaced leaflets is unknown. Data from the PARTNER trial at 2 years shows stable aortic gradients and areas[5]; for the critically ill patients approved for treatment by the FDA, this may not be an issue at this time. However, if use of TAVI is expanded to younger patients with the expectation of a long survival, close observation will be required for monitoring of restenosis, stroke, and more periprosthetic leaks due to the unstable nature of this calcified material

The serious problem of moderate to severe periprosthetic leakage after TAVI has been mentioned above. This occurs in some cases mainly because the implantation process is unable to turn the diseased orifice, which is trefoil or triangular in shape, into a circle to match the deployed prosthesis (Figure 3).[15] The backwashing of blood across the calcified tissue has led to erosion of residual calcium and enlargement of periprosthetic leaks after conventional aortic valve replacement.

Undoubtedly, this problem will eventually be solved with a prosthesis or prosthetic annulus that is more conforming. It is now well recognized that some patients are unsuitable for TAVI because of the pathoanatomy of their calcified aortic roots and leaflets (Figure 1). Detailed preoperative CT studies of the aortic root are considered essential to avoid displacement into the coronary ostia of calcified masses (Figure 1 D).

Clinical Perspective

While TAVI has proven to be a valuable addition to the care of patients with "inoperable" aortic stenosis, it is important to note that the risk of conventional AVR surgery in these patients is declining due to a variety of factors. During preoperative patient selection and evaluation, there is a significant focus on assessing the patient's frailty, neurocognitive reserve, and recent history of activity and independent living.[16] The important concept of identifying patients "dying with" rather than "dying of " aortic stenosis has been proposed. It seems that in the future, TAVI will not be offered to some of the most severely ill patients who have had very short survival times despite successful TAVI. Screening is routinely performed for carotid and coronary atherosclerosis. Renal function is evaluated and optimized if possible, and pulmonary function is critically assessed. Intraoperative management has progressed considerably with regard to stroke avoidance and pulmonary complications. Myocardial protection and management of the significant diastolic dysfunction routinely seen in these patients is better understood.

Postoperative care has undergone a complete revolution in the last 10 years. Our patients receive care 24 hours a day by our in-house, full-time CV surgical intensivist team. This has led to superior management of the postoperative period. Programmatic goals to avoid ventilator-dependent pneumonia, ICU-acquired infections, sepsis, and excessive blood usage have all had incremental benefit. Aggressive and early management of hemodynamic instability with prompt availability of echocardiography has assisted these patients. Early mobilization, nutritional support, and a formal perioperative physical therapy program have aided recovery. Thus, significant improvements in care have lowered the historical morbidity and mortality of these elderly patients. The commitment to a collaborative team-based approach is essential for the care of these critically ill patients.

Expansion of Indications for TAVI

Expanding the role of TAVI from treatment of inoperable patients with aortic stenosis to other less-sick populations has been studied in two randomized prospective trials. In the PARTNER Cohort A trial for high-risk patients, described in detail above, the conventional AVR results were competitive with TAVI at 1 year in terms of mortality.[6] However, excess stroke and paravalvular leaks remain a problem in TAVI patients. The ultimate magnitude of these problems and the risk of progressive aortic insufficiency will be answered by ongoing follow-up for the Cohort A, such as the 2-year data mentioned above for the Cohort B patients.

In a study of stroke after TAVI in 253 patients, Tay et al.[17] showed that while the incidence of stroke was highest in the first 24 hours, it remained high for 2 months post-procedure. Proposed mechanisms for perioperative strokes included embolization of atheromatous or calcific debris and periprocedural hypotension. Later strokes were attributed to thrombus formation on the prosthesis or in periprosthetic spaces.

The STACCATO trial[18] compared transapical TAVI with surgical AVR in elderly patients (mean age: TAVI 80 ± 3.6 and AVR 82 ± 4.4 years), all of whom had severe aortic stenosis but who were otherwise not at an elevated risk for surgical AVR. The mean STS score was 3.3. Of the original 200 patients planned to be enrolled, 70 patients were treated and then the trial was terminated by the Data Safety and Monitoring Board. Of the 70 patients, 34 underwent transapical TAVI and 36 underwent surgical AVR. The primary endpoint of all-cause mortality, stroke, and renal failure requiring dialysis was elevated in TAVI vs. AVR: 14.7% vs. 2.8%, $P = 0.07$. Death rate for TAVI was higher (8.8% vs. 0%) as was stroke (5.9% vs. 2.8%). The incidence of moderate/severe aortic insufficiency was 13% vs. 0%. The authors of this small trial concluded that in these lower-risk elderly patients, transapical TAVI may be inferior to surgical AVR. These surgical results resemble those obtained in our own series of elderly (>80 years) surgical AVR patients.

Conclusion

While TAVI seems like a low-risk and simple catheter-based therapy compared with surgical AVR, it is still in its developmental phase and should be considered a major intervention with the risks of serious early and late complications. It is of proven value in the care of patients considered to be inoperable because of extensive irreversible comorbidities or frailty.[16] We feel that in experienced centers, conventional surgery is feasible in most patients despite advanced age. In our own data, age alone has not been a predictor of mortality, but rather mortality is associated with easily identifiable extensive comorbidities and frailty. It is generally agreed that patients should be seen for a surgical evaluation before a final decision is made to employ TAVI.

This recommendation is in agreement with that of the FDA, which has approved TAVI only for treatment of inoperable patients. Both conventional AVR and TAVI will continue to improve. Results of ongoing and future studies will influence patient selection for each of these valuable therapies.

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